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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/982,320	10/17/2001	Michael J. Russell	9721.9544B	6571

7590

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EXAMINER

GIBSON, ROY DEAN

ART UNIT	PAPER NUMBER
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3739

DATE MAILED: 02/25/2004

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/982,320

Applicant(s)

RUSSELL, MICHAEL J.

Examiner

Roy D. Gibson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 November 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19, 21-23, 30, 32-35, 46-48 and 50-66 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 19 is/are allowed.
- 6) ☐ Claim(s) 21-23, 30, 33-35, 46-48 and 50-66 is/are rejected.
- 7) ☐ Claim(s) 32 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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Entry of Amendment

Applicant's amendment filed on Nov. 5, 2003, as Paper No. 6, is acknowledged. Claims 1-18, 20, 24-29, 31, 36-45 and 49 have been canceled and claims 50-66 have been added by the Applicant, thus claims 19, 21-23, 30, 32-35, 46-48 and 50-66 are currently pending.

Prior Rejections or Objections

The following comments pertain to the rejections or objections in the most recent Office action, Paper No. 4, mailed on June 6, 2003. Rejections under 35 U.S.C. 112, 102 and 103 are withdrawn, however, new grounds of rejection are presented below.

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 21, 22, 30, 50, 53, 59 and 61 are rejected under 35 U.S.C. 102(b) as anticipated by Ogle (3,605,728).

As to claims 21, 22, 30, 53, 59 and 61, Ogle discloses a medical electrode comprising:

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a distal end for connecting to a medical device; a separable structure of the conventional snap-on type at the proximal end of the electrode; a conductive lead connected between the distal and proximal ends; and a current stoppage means being connected to the second member (Figure 2, # 22 and col. 1, line 24-col. 2, line 9, and lines 30-56 and col. 3, line 17-25).

As to claim 50, Ogle further discloses the electrode can be configured as a plate (Figure 3 and col. 2, lines 41-44).

Claim Rejections - 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 30 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller (3,986,495). Miller discloses the medical device essentially as claimed and implies that such an electrode is designed to prevent pick-up from other medical equipment in the surgical environment (col. 2, lines 33-63). Thus the examiner maintains that one of ordinary skill in the art would know to locate the current stoppage means, including a diode, immediately adjacent to the proximal end of the electrode (col. 3, lines 8-57). Also see Olge, col. 2, lines 61-64.

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Claims 30, 34, 35, 46-48 and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Day (3,603,811).

As to claims 30, 34, 46 and 57, Day discloses a current limiter for a medical electrode essentially as claimed and specifically that a fuse could be used as a current limiter with the limitation of loss of monitoring (col. 1, lines 4-57 and col. 2, lines 7-22). Further to claims 35, 47 and the examiner maintains that one of ordinary skill in the art would know to select an indicator fuse to determine if the fuse had been blown.

As to claim 48, Day further discloses that the limit of allowable current in this application is about 10 - 100 milliamperes or including approximately 1/16 amperes as required by the application (col. 1, lines 19-25).

Claim 51 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ogle in view of Moberg (5,265,607). Ogle discloses the medical electrode essentially as claimed except for the proximal end including a portion in the shape of a needle. But, Moberg discloses a sensing electrode whose proximal end is a needle which can be inserted into a patient's head subcutaneously (col. 1, lines 25-44). Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the device of Ogle, as taught by Moberg, to provide a means to attach the electrode to the patient's head as required.

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Claims 52 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ogle in view of Axelgaard (5,785,040). Ogle discloses the medical electrode essentially as claimed and detailed above, but lacks a portion at the proximal end formed in the shape of a strap. However, Axelgaard discloses a medical electrode assembly (Figure 9) wherein a portion of the electrode at the proximal end is formed in the shape of a strap (76 and 78) for applying the electrode with compression to the patient (col. 9, 55-col. 10, lines 22). Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the device of Ogle, as taught by Axelgaard, to provide a strap as a means to attach the electrode to the patient.

Claim 54 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ogle in view of Danby et al. (4,741,344). Ogle discloses the medical electrode essentially as claimed and detailed above, but lacks a portion at the proximal end formed in the shape of an ear plug. But, Danby et al. disclose an ear canal electrode or earplug electrode for conducting electrical signals picked up from the ear canal epidermal surface (col. 4, lines 13-58). Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the device of Ogle, as taught by Danby et al., to provide an earplug as a means to attach the electrode to the patient's ear.

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Claim 55 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ogle in view of Heil, Jr, et al. (5,085,218). Ogle discloses the medical electrode essentially as claimed and detailed above, but lacks a portion at the proximal end formed in the shape of an ear plug. But, Heil et al. disclose an electrode with a corkscrew for conducting electrical signals from myocardial tissue when implanted therein. Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the device of Ogle, as taught by Heil et al., to provide a corkscrew electrode as a means to attach the electrode to the patient's heart.

Claim 56 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ogle in view of Hon (5,511,546). Ogle discloses the medical electrode essentially as claimed except for the proximal end including a portion in the shape of a clip. But, Hon discloses a clip at the proximal end of a medical electrode for accepting a finger for taking an ECG through the finger of the patient (Figure 13, col. 5, line 28-col. 6, line 17). Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the device of Ogle, as taught by Hon, to provide a means to attach or clip the electrode to the patient.

Claims 23, 58, 62 and 64-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ogle in view of Day. Ogle fails to disclose a fuse as the current

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stoppage means, but Day teaches a fuse could be used in spite of its limitations as is also well known in the art (col. 1, lines 4-57 and col. 2, lines 7-22).

Claims 60, 63 and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ogle. Ogle discloses the current stoppage means is located on the top member of the snap-on electrode, but the examiner maintains that positioning of the current stoppage means on the bottom member would be merely a design choice, which would not produce any unexpected results, or advantages and further that either of the connector members could be male or female.

Allowable Subject Matter

Claim 19 is allowed.

Claim 32 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Bonner et al. 95,968,086) disclose a medical lead for sensing

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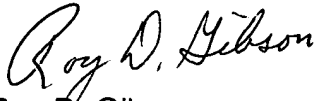
including diodes at the end; and Jacobson (5,833,710) discloses a protection circuit for an implantable electrode device which includes a diode.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy Gibson whose telephone number is (703) 308-3520. The examiner can normally be reached on Monday-Friday from 9 am - 4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Linda Dvorak, can be reached on (703) 308-0994. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0858.

February 17, 2004


Roy D. Gibson
Patent Examiner
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